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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/210,031	12/11/1998	ATTILA T. LORINCZ	2629-4005US1	6182
7590	09/15/2004		EXAMINER	
MORGAN & FINNEGANT 345 PARK AVENUE NEW YORK, NY 10154			BRUSCA, JOHN S	
		ART UNIT	PAPER NUMBER	
		1631		

DATE MAILED: 09/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/210,031	LORINCZ ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	John S. Brusca	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

#### A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 36-75 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_ is/are allowed.
- 6) Claim(s) 36-49 and 51-75 is/are rejected.
- 7) Claim(s) 50 is/are objected to.
- 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 27 August 2003 is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
    - a) All    b) Some \* c) None of:
      1. Certified copies of the priority documents have been received.
      2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.
      3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                     | Paper No(s)/Mail Date: ____ .   |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date: ____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: ____ .                                   |

## **DETAILED ACTION**

1. The finality of the Office action mailed 10 October 2003 is withdrawn because the status of claim 50 was improperly listed as allowed on the Office action summary. Claim 50 is objected to in this Office action to correct the record.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 36-48, 51-54, 58, 59, and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dunphy.

The claims are drawn to cell collection medium comprising alcohol, a cross-linking agent, and a chelator. In some embodiments the medium is buffered at neutral or acidic pH levels. In some embodiments particular volumes of medium are claimed, and medium that inhibits RNA, DNA, or protein degradation is claimed.

Dunphy shows in example 4, columns 7 and 8, a medium for fixing tissue for histological procedures. The aqueous medium comprises 3.5-4% ethanediol, a cross-linking fixative, and 15-25% ethanol. Dunphy shows in column 5, lines 1-7 that a chelating agent EDTA is a useful addition because it acts as a bacteriostatic agent and because it inhibits bacterial enzymatic activity. Dunphy shows that is desirable to add a buffering agent in column 6 to buffer to pH 6.8-7.8, and further shows to use media with an acidic pH in column 3, lines 18-19 and column 4, lines 16-18. Dunphy does not explicitly show a medium for tissue collection that comprises EDTA, or is buffered to neutral or acidic pH levels.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the tissue collection medium of Dunphy in example 4 by addition of buffer and EDTA, because Dunphy shows that buffering agents may be used to adjust the pH to neutral or acidic levels for tissue fixation media as desired, and because Dunphy shows that EDTA has a bacteriostatic effect that is desirable in a tissue fixation medium. It would have been further obvious to use any of the recited volumes of medium in the claims as dictated by the size of the tissue sample. It would have been further obvious that inhibition of bacterial enzymatic

activity by EDTA and cross-linking agents would inhibit enzymatic degradation of RNA, DNA, and protein.

6. Claims 36, 37, 42, 49, 55-60, and 68-75 are rejected under 35 U.S.C. §103(a) as being unpatentable over Dunphy as applied to claims 36-48, 51-54, 58, 59, and 61 above, and further in view of Weber in view of Harrison.

The claims are drawn to tissue collection media comprising a cross-linking agent consisting of formaldehyde or glutaraldehyde, and their methods of use.

Dunphy as applied to claims 36-48, 51-54, 58, 59, and 61 above does not show methods of using tissue treated in collection medium of DNA and protein analysis. Dunphy as applied to claims 36-48, 51-54, 58, 59, and 61 above does not show cross-linking agents consisting of formaldehyde or glutaraldehyde.

Weber et al. shows on page 8 a tissue collection medium useful for *in situ* hybridization studies. Weber et al. shows that the medium may comprise a cross-linking fixative at a level of less than 10%, and suggests use of formalin (formaldehyde) as a cross-linking fixative.

Harrison shows discloses a tissue collection medium comprising glutaraldehyde as a cross-linking fixative at a level up to 1%. Harrison shows in column 4 that tissue treated in collection medium may be used in *in situ* antigen assays.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use tissue samples treated with the collection medium of Dunphy for methods of DNA and antigen analysis because Weber shows that such media can be used for DNA hybridization analysis and Harrison shows that such media may be used for antigen analysis. It would have been further obvious to use a cross-linking agent consisting of

formaldehyde or glutaraldehyde because Weber and Harrison respectively show that such aldehydes are useful cross-linking agents in tissue collection media that are compatible with further analysis of DNA or protein.

7. Claims 58, 59, and 62-66 are rejected under 35 U.S.C. §103(a) as being unpatentable over Dunphy as applied to claims 36-48, 51-54, 58, 59, and 61 above, and further in view of Wainwright.

The claims are drawn to containers comprising collection medium as claimed in claims 58 or 59, a lid, and a brush.

Dunphy as applied to claims 36-48, 51-54, 58, 59, and 61 above does not show a container comprising collection medium as claimed in claims 58 or 59, a lid, and a brush.

Wainwright shows a container, a lid fitting the container, and a brush for preserving a cell sample and comprising a pap unit.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use the container of Wainwright with the tissue collection medium of Dunphy as applied to claims 36-48, 51-54, 58, 59, and 61 above because Wainwright shows that such containers are convenient for obtaining pap samples for subsequent analysis.

8. Claim 67 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dunphy as applied to claims 36-48, 51-54, 58, 59, and 61 above and further in view of Wainwright as applied to claims 58, 59, and 62-66 above, and further in view of Weber in view of Harrison.

The claims are drawn to containers comprising collection medium as claimed in claims 58 or 59 further comprising a cross-linking agent consisting of formaldehyde or glutaraldehyde, a lid, and a brush.

Weber et al. shows on page 8 a tissue collection medium useful for in situ hybridization studies. Weber et al. shows that the medium may comprise a cross-linking fixative at a level of less than 10%, and suggests use of formalin (formaldehyde) as a cross-linking fixative.

Harrison shows discloses a tissue collection medium comprising glutaraldehyde as a cross-linking fixative at a level up to 1%. Harrison shows in column 4 that tissue treated in collection medium may be used in in situ antigen assays.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the container comprising tissue collection medium of Dunphy as applied to claims 36-48, 51-54, 58, 59, and 61 and further in view of Wainwright as applied to claims 58, 59, and 62-66 above by use of cross-linking agents consisting of formaldehyde or glutaraldehyde because Weber and Harrison respectively show that such aldehydes are useful cross-linking agents in tissue collection media that are compatible with further analysis of DNA or protein.

9. Applicant's arguments filed 27 August 2003 have been fully considered but they are not persuasive. The applicants point to intended use limitations in the claims and argue that the applied prior art does not show such limitations. However, intended use limitations that do not affect the structure of the claimed compositions are not given patentable weight (see MPEP 2111.02). The applicants have not provided evidence that the compositions obvious over the cited prior art do not meet the limitations of the preamble of the claims and the rejections are maintained. The applicants state that claim 67 is not obvious because Weber discloses reagents that are incompatible with protein analysis, however claim 67 is not limited to protein analysis.

***Allowable Subject Matter***

10. Claim 50 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

11. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center at (800) 786-9199.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca whose telephone number is 571 272-0714. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on 571 272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*John S. Brusca 9 September 2004*  
John S. Brusca  
Primary Examiner  
Art Unit 1631

jsb